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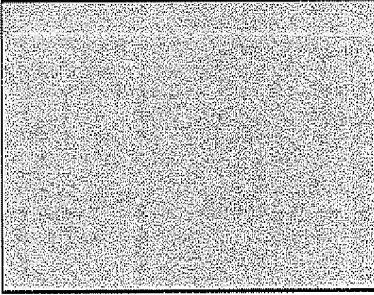
INAD 10-708 / NADA 141-327
LONGRANGE™ (eprinomectin) Extended-Release Injectable Parasiticide for Cattle
Regulatory History

	Date	Correspondence	Sender	Recipient	Content
INAD	02 Feb 2000	I-010708-A-0000	Merial	CVM	Request for INAD
	09 Feb 2000	---	CVM	Merial	Opening of INAD 10-708
Effectiveness	12 Oct 2004	I-010708-P-0121	Merial	CVM	Effectiveness technical section
	14 Jun 2005	---	CVM	Merial	Complete letter
	29 Mar 2007	I-010708-P-0154	Merial	CVM	Data supporting enhanced claims against select parasites
	03 Oct 2007	---	CVM	Merial	Incomplete letter
	23 Feb 2009	I-010708-P-0171	Merial	CVM	Response to incomplete letter
	21 Aug 2009	---	CVM	Merial	Complete letter
	30 Dec 2002	I-010708-P-0084	Merial	CVM	1,3,5x TAS study
Target Animal Safety	22 Oct 2003	---	CVM	Merial	Incomplete letter
	28 May 2004	I-010708-P-0113	Merial	CVM	Response to incomplete letter
	14 Jan 2005	---	CVM	Merial	Study acceptable letter
	20 Dec 2005	I-010708-P-0139	Merial	CVM	Cow reproductive safety study (estral)
	30 Jun 2006	---	CVM	Merial	Incomplete letter
	20 Dec 2006	I-010708-P-0149	Merial	CVM	Response to incomplete letter
	19 Jun 2007	---	CVM	Merial	TAS technical section complete letter
	20 Dec 2005	I-010708-P-0140	Merial	CVM	Cow reproductive safety study (gestational)
	07 Jul 2006	---	CVM	Merial	Incomplete letter
	20 Dec 2006	I-010708-P-0148	Merial	CVM	Response to incomplete letter
	19 Jun 2007	---	CVM	Merial	TAS technical section complete letter

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Human Food Salmon	14 Dec 2000	I-010708-O-0050	Merial	CVM	Request for slaughter authorization
	30 Aug 2001	I-010708-T-0065	Merial	CVM	Amendment
	26 Oct 2001	---	CVM	Merial	Granting of slaughter authorization
	26 Aug 2004	---	CVM	Merial	Rescinding of slaughter authorization
	02 Aug 2007	I-010708-D-0158	Merial	CVM	Request for reinstatement of slaughter authorization
	19 Nov 2007	---	CVM	Merial	Reinstatement of slaughter authorization
	15 Jan 2008	I-010708-D-0160	Merial	CVM	Request to add animals to slaughter authorization
	14 Apr 2008	---	CVM	Merial	Amendment to slaughter authorization to add animals
	30 Nov 2001	I-010708-H-0070	Merial	CVM	EPR acute reference dose study in rats
	19 Mar 2002	---	CVM	Merial	Response: Establishment of ASDI and SC _{is}
	13 Oct 2003	I-010708-P-0101	Merial	CVM	EPR radioresidue depletion study
	19 Mar 2004	---	CVM	Merial	Concurrence on target tissue and marker residue
	31 Mar 2004	I-010708-P-0109	Merial	CVM	Request for application of ASDI and maintenance of published tolerance
	29 Apr 2004	---	CVM	Merial	Concurrence
	20 Aug 2004	I-010708-P-0119	Merial	CVM	EPR marker residue depletion study
	22 Oct 2004	---	CVM	Merial	Response: Tentatively established withdrawal period 48 days
	25 Jun 2003	I-010708-P-0096	Merial	CVM	NMP summary reports from EPA's TSCA database
	29 Jan 2004	---	CVM	Merial	Response: Need for statistical analysis of data from Malley et al. (2001) study
	04 Aug 2004	I-010708-P-0117	Merial	CVM	NMP human hazard, exposure, and risk characterization
	21 Dec 2004	---	CVM	Merial	Response: Request for additional data to support NMP MOA for carcinogenicity in mouse
	20 Dec 2005	I-010708-P-0138	Merial	CVM	NMP MOA studies
	21 Jul 2006	---	CVM	Merial	Response: NMP will be regulated as a carcinogen despite MOA
	26 Mar 2007	I-010708-P-0153	Merial	CVM	NMP POD paper
	21 Sep 2007	---	CVM	Merial	Response: Human health protective value assigned
	16 May 2007	I-010708-P-0156	Merial	CVM	Paper supporting marker-to-total ratio
	08 Nov 2007	---	CVM	Merial	Response: Acceptance of marker residue, target tissue, and marker-to-total ratio

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	22 Sep 2003	I-010708-P-0100	Merial	CVM	EPR regulatory method
	09 Jul 2004	---	CVM	Merial	Incomplete letter
	08 Mar 2005	I-010708-P-0127	Merial	CVM	Response to incomplete letter
	22 Nov 2005	---	CVM	Merial	Response: Determinative method accepted and confirmatory method response pending Office of Research report PR&D 0111101 and remaining EPR regulatory method info
	11 Jul 2008	I-010708-P-0163	Merial	CVM	Incomplete letter
	08 Jan 2009	---	CVM	Merial	Response to incomplete letter
	01 Jul 2009	I-010708-P-0176	Merial	CVM	Complete letter
	07 Oct 2009	---	CVM	Merial	Complete letter
	06 Aug 2008	---	Merial	CVM	NMP regulatory method with Merial validation data
	13 Aug 2009	I-010708-P-0180	Merial	CVM	NMP post-trial method validation data and request for complete letter
	04 Feb 2010	---	CVM	Merial	ERA request
	08 Mar 2010	Unknown	Merial	CVM	ERA
	07 May 2010	---	CVM	Merial	Complete letter

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Environmental Safety	25 Jun 2003	Unknown	Merial	CVM	Environmental Assessment
	22 Jan 2004	I-010708-P-0106	Merial	CVM	Amendment 1 of 2
	22 Jan 2004	I-010708-P-0107	Merial	CVM	Amendment 2 of 2
	23 Jul 2004	---	CVM	Merial	Incomplete letter
	02 Aug 2004	I-010708-P-0115	Merial	CVM	Response
	24 Feb 2005	---	CVM	Merial	Complete letter
Chemistry, Manufacturing, and Controls (CMC)	18 Aug 2010	I-010708-P-0192	Merial	CVM	Request for new FONSI and complete letter
	06 Oct 2010	---	CVM	Merial	Complete letter
	12 Aug 2004	I-010708-P-0118	Merial	CVM	CMC technical section
	26 Jan 2005	---	CVM	Merial	Incomplete letter
	10 Jun 2005	I-010708-P-0135	Merial	CVM	Response to incomplete letter
	17 Feb 2006	---	CVM	Merial	Incomplete letter
	07 May 2007	I-010708-P-0155	Merial	CVM	Response to incomplete letter
	13 Nov 2007	---	CVM	Merial	Incomplete letter
	10 Apr 2009	I-010708-P-0172	Merial	CVM	Response to incomplete letter
	08 Oct 2009	---	CVM	Merial	ERA request
	02 Nov 2009	I-010708-T-0182	Merial	CVM	ERA
	07 Jan 2010	---	CVM	Merial	Incomplete letter
	31 Mar 2010	I-010708-P-0184	Merial	CVM	Response to incomplete letter
	24 Sep 2010	---	CVM	Merial	ERA request
	15 Oct 2010	I-010708-T-0197	Merial	CVM	ERA
	22 Dec 2010	---	CVM	Merial	Complete letter
All Other Information	11 Jun 2010	I-010708-M-0186	Merial	CVM	All Other Information technical section
	28 Oct 2010	I-010708-T-0198	Merial	CVM	Amendment
	25 Feb 2011	---	CVM	Merial	Complete letter
Labeling	30 Jun 2010	I-010708-M-0187	Merial	CVM	Labeling technical section
	03 Aug 2010	I-010708-T-0191	Merial	CVM	Minor amendment 1 of 3
	07 Sep 2010	I-010708-T-0193	Merial	CVM	Minor amendment 2 of 3
	03 Jan 2011	I-010708-T-0200	Merial	CVM	Minor amendment 3 of 3
FOI Summary	25 Feb 2011	I-010708-Q-0196	CVM	Merial	CVM's FOI Summary
NADA	30 Mar 2011	Unknown	Merial	CVM	Administrative NADA (converted by CVM to traditional NADA)
	26 Sep 2011	---	CVM	Merial	Approval